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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,969	07/23/2003	Brent A. Johnson	17592 (AP)	1610

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EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,969	JOHNSON, BRENT A.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/23/03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) 19-27 and 38 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 and 28-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~7/23/03~~. 1/6/04, 3/19/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

The Office Action is in response to the Preliminary Amendment filed July 23, 2003. Claims 1-38 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18 and 28-37 drawn to a heterogeneous pharmaceutical composition comprising a carboxylic acid, a peroxide, and multiplicity of solid particles, classified in class 424, subclass 401.

II. Claims 19-27 and 38, drawn to a method of preparing a pharmaceutical composition comprising a carboxylic acid, a peroxide, and multiplicity of solid particles , classified in class 424, subclass 401.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case another materially different product, e.g. a dentifrice composition, can be made using the method herein.

Because these inventions are distinct for the reasons given, restriction for examination purposes as indicated is proper. It is noted that while the searches

of Groups I and II may be overlapping, there is no reason to believe that the searches are co-extensive. In searching Group I, the Examiner will be focusing on the patentability of the pharmaceutical composition, and not the method of preparing the pharmaceutical composition. Conversely, in searching Group II, the Examiner will be focusing on the patentability of the method of preparing the pharmaceutical composition and not the pharmaceutical composition. Accordingly, a search for the groups would pose an undue burden on the Office.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

During a telephone conversation with Mr. Brent Johnson on May 15, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18 and 28-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-27 and 38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-18, 28-32, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sefton (US Pat. No. 6,262,117 B1) in view of Shefer et al. (US Pat. No.6,825,161 B2), and further in view of Hawley's Condensed Chemical Dictionary.

Sefton teaches serially applying azelaic acid (carboxylic acid) and benzoyl peroxide (peroxide) topical compositions for treatment of acne. Additionally, the

benzoyl peroxide is more preferably used as a hydrous (water containing) benzoyl peroxide and is preferably suspended in the form of microparticles (solid particles) (column 2, lines 33-35), recited in claims 1, 2, 4, 6, and 16. Though water is not explicitly taught by the reference, compositions in hydrous form contain water and therefore, claim 28 is rendered obvious by the reference. The prior art teaches the anti-acne composition in the absence of retinoids (column 8, lines 24-27 -- claim 1), as recited in claim 36.

The reference teaches the combination of azealic acid and benzoyl peroxide in a single topical composition provides ease of application (column 7, lines 50-53 and column 8, lines 24-27).

However, in the Background of the Art, Sefton teaches benzoyl peroxide has an inherent problem of decomposing coingredients in topical formulations to thereby cause itching upon application (column 1, lines 58-60). Additionally, the reference teaches benzoyl peroxide suspended in the form of microparticles (solid particles), (column 2, lines 33-35) but the reference fails to teach a composition comprising both benzoyl peroxide suspended in the form of microparticles (solid particles) and a carboxylic acid. Also, the reference fails to teach the size of the microspheres.

Shefer et al. teaches a method of controlling the release rate of an active agent, as well as fragrances in soap bar products and soap compositions (topical agents) (column 6, lines 1-3). The active agents are incorporated into nanosphere matrices (solid particles), that are encapsulated in moisture sensitive microspheres (solid particles) (see abstract). Components incorporated in the

matrices (solid particles) are cosmetic, dermatological, or pharmaceutical active agents. Further, the prior art teaches active agents include anti-acne actives such as salicyclic acid, benzoyl peroxide, and azealic acid (column 17, lines 1-10). The reference teaches the material forming the nanosphere (solid particles) are "inert nontoxic hydrophobic materials with a melting point between about 20 degrees C and about 90 degrees C," recited in claims 10-14, and 37. Examples of hydrophobic materials (solid particles) include animal waxes such as beeswax (column 13, lines 4-10), recited in claim 9. The reference, teaches in Example 2, jojoba oil as a component of the controlled release system (see column 26, lines 64-67). The jojoba oil is encapsulated in the hydrophobic nanosphere and a powder floral fragrance is encapsulated in the microsphere (see column 26, lines 20-25), as recited in claim 17.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the teaching of Sefton by incorporating one active agent in the solid particles because Sefton teaches suspension of an active agent in microparticles (solid particles) is preferable and also, the reference teaches benzoyl peroxide has an inherent problem of decomposing coingredients in topical formulations to thereby cause itching upon application. The motivation to make the incorporation is found in the Shefer et al. reference because it teaches the matrix material provide good barrier properties, low toxicity and irritancy, stability, and high loading capacity for the active agents (column 3, lines 11-15). Therefore, the skilled artisan would have had a reasonable expectation of successfully producing a composition with good barrier

properties, low toxicity and irritancy, stability, and high loading capacity for the anti-acne active agents.

Additionally, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the teaching of Sefton by incorporating specific solid particles because Sefton teaches suspension in the form of microparticles (solid particles) is preferable but fails to teach specific types of solid particles. The motivation to incorporate the specific microparticles (solid particles) is found in the Shefer et al. reference because it teaches beeswax as a suitable solid core material and the matrix material provide good barrier properties, low toxicity and irritancy, stability, and high loading capacity for the active agents (column 3, lines 11-15). Therefore, the skilled artisan would have had a reasonable expectation of successfully producing a composition with good barrier properties, low toxicity and irritancy, stability, and high loading capacity for the anti-acne active agents using the said solid particles.

Shefer et al teaches the size of the nanospheres of the claimed invention but fails to teach the size of the microspheres that encapsulate the nanospheres. However, by definition microspheres are in the micron size range (20–150u) or (0.02mm to 0.15 mm), and therefore meet the instant claims 7, 8, and 18 (See attached copy, Hawley's Condensed Chemical Dictionary).

The limitation "wherein said composition is useful for treating acne," in claim 1, is an intended use and receives no patentable weight in the composition claim.

The limitation "a package is suitable for dispensing the therapeutically active agents" recited in claim 28 does not further limit the composition. The container for storage of the pharmaceutical composition is immaterial to the claimed invention and therefore receives no patentable weight in a composition claim. Additionally, limitations of the package recited in claims 29-32 receive no patentable weight.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sefton (US Pat. No. 6,262,117 B1) in view of Shefer et al. (US Pat. No.6,825,161 B2) and Hawley's Condensed Chemical Dictionary, as applied to claims 1-4, 6-18, 28-32, 36 and 37above, and further in view of Johnson (US Pat. No. 6,414,032 B1).

Sefton, Shefer et al., and Hawley's Condensed Chemical Dictionary are as discussed above.

Sefton teaches humectants such as glycerin, propylene glycol, polyethylene glycol.

Sefton does not expressively teach the said humectants as viscosity enhancing agents.

Johnson teaches polyethylene glycols and polypropylene glycols as components in an antiseptic composition suitable for topical administration to the skin. The reference teaches the ingredients are widely used in order to increase viscosity or to increase the tackiness of a composition. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was

made to employ the humectants of Sefton's invention with the expectation of producing a viscous enhanced composition.

Claims 5, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sefton (US Pat. No. 6,262,117 B1) in view of Shefer et al. (US Pat. No.6,825,161 B2) and Hawley's Condensed Chemical Dictionary, as applied to claims 1-4, 6-18, 28-32, 36 and 37 above, and further in view of Maibach et al. (Pub No. US2003/0077301 A1).

Sefton, Shefer et al., and Hawley's Condensed Chemical Dictionary are as discussed above.

Sefton and Shefer et al. do not specifically teach hydrogen peroxide, or tazarotene as components in the composition.

Maibach et al. teaches topical agents employed to treat acne include hydrogen peroxide, retinoids such as tazarotene, antibiotic such as azelaic acid (page 1, paragraph [0010], lines 1-19).

Thus Maibcah teaches the equivalence of the various agents used for treating acne. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Sefton composition by substituting the benzoyl peroxide with hydrogen peroxide, and employing tazarotene, as an ethyl ester of a carboxylic acid. The motivation to make such a substitution is because benzoyl peroxide, hydrogen peroxide, and tazarotene are all active agents employed for making compositions to treat acne and substituting one active agent with another is with the expectation of similar efficacy in the treatment of acne.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER